PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox Palatable Drops, Powder for Oral Suspension 50mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains Amoxicillin Trihydrate equivalent to 750 mg amoxicillin.

3. PHARMACEUTICAL FORM

Powder for oral suspension

4. PACKAGE SIZE

15 ml

5. TARGET SPECIES

Dogs
Cats

6. INDICATION(S)

For the control of infections in dogs and cats, including infections of the alimentary tract, respiratory tract and urogenital tract, eye and ear infections, and skin and wound infections.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid under dosing.

The powder should be reconstituted with 12 ml water to give a 15 ml suspension containing amoxicillin at a concentration of 50 mg/ml.

FOR ORAL ADMINISTRATION TO DOGS AND CATS: 1 ml per 5 kg bodyweight twice daily for up to seven days.

Shake well before use

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer to penicillin sensitive animals. As with other penicillins amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised when used in any other small herbivores.

Operator warnings:

Penicillins/Cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warning.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store the powder or reconstituted product above 25ºC; any reconstituted product remaining 7 days after preparation should be discarded.
Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of part used and empty bottles in the household refuse. Unused product should be returned to the veterinary surgeon.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For Animal Treatment Only

POM-V

To be supplied only by veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4101

17. MANUFACTURER'S BATCH NUMBER

Bn.:
D.O.M.:

Further Information: See package leaflet.

Once re-constituted, use by: dd/mm/yy

Distributed by:

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby, Northamptonshire,
NN18 9EX
United Kingdom

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox Palatable Drops, Powder for Oral Suspension 50mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Amoxicillin Trihydrate equivalent to 750 mg amoxicillin.

3. PHARMACEUTICAL FORM

Powder for oral suspension

4. PACKAGE SIZE

15 ml

5. TARGET SPECIES

Dogs
Cats

6. INDICATION(S)

For the control of infections in dogs and cats, including infections of the alimentary tract, respiratory tract and urogenital tract, eye and ear infections, and skin and wound infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The powder should be reconstituted with 12 ml water to give a 15 ml suspension containing amoxicillin at a concentration of 50 mg/ml.

For oral administration to dogs and cats: 1 ml per 5 kg bodyweight twice daily for up to seven days.
Shake well before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer to penicillin sensitive animals. As with other penicillins amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised when used in any other small herbivores.

Operator warnings

Penicillins/Cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warning.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store the powder or reconstituted product above 25ºC; any reconstituted product remaining 7 days after preparation should be discarded.
Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of part used and empty bottles in the household refuse. Unused product should be returned to the veterinary surgeon.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For Animal Treatment Only

POM-V

To be supplied only by veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4101

17. MANUFACTURER'S BATCH NUMBER

Bn.:
D.O.M.:

Further Information: See package leaflet.

Distributed by:

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby, Northamptonshire,
NN18 9EX
United Kingdom

PACKAGE LEAFLET FOR:

Betamox Palatable Drops, Powder for Oral Suspension 50 mg/ml

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox Palatable Drops, Powder for Oral Suspension 50 mg/ml

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Betamox Palatable Drops are presented as a pale red powder containing Amoxicillin Trihydrate equivalent to 750mg amoxicillin.

The powder should be reconstituted with 12 ml water to give a 15 ml suspension containing amoxicillin at a concentration of 50 mg/ml.

4. INDICATION(S)

Amoxicillin is a broad-spectrum semi-synthetic penicillin, bactericidal in action. *In vitro* it is effective against a wide range of Gram-positive and Gram-negative bacteria found in dogs and cats including: *Bacillus cereus*, *Bordetella bronchiseptica*, *Corynebacterium* spp, *Citrobacter freundii*, *Chromobacter* spp, *Escherichia coli*, *Flavobacter* spp, *Proteus mirabilis*, *Pasteurella* spp, including *Pasteurella multocida*, *Salmonella* spp, *Staphylococci* (penicillin-sensitive strains) and *Streptococci*.

Betamox Palatable Drops are suitable for the control of infections only in dogs and cats caused by susceptible organisms including: infections of the alimentary tract, respiratory tract and urogenital tract; eye and ear infections and skin and wound infections.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

5. CONTRAINDICATIONS

Betamox Palatable Drops should not be given to penicillin sensitive animals.

As with other penicillins, amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised when used in any other small herbivores.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs
Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid under dosing.
Administer orally, using the graduated pipette provided, at a rate of 10 mg/kg bodyweight, twice daily for up to seven days.
The dosage rate of 10 mg/kg is achieved by administering 1 ml of reconstituted product per 5 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitution: Add 12 ml water to the powder and shake vigorously. This will make 15 ml of the suspension, containing amoxicillin at a concentration of 50 mg/ml.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store the powder or reconstituted product above 25ºC.
Keep container in outer carton
Shake well before use.
Any reconstituted product remaining 7 days after preparation should be discarded.
After the product is reconstituted, using the in-use shelf-life which is specified on this package leaflet, the date on which any reconstituted product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton.

12. SPECIAL WARNING(S)

Operator warning - Penicillin/cephalosporin sensitivity:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to Penicillins may

lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitized, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

For Animal Treatment Only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of part used and empty bottles in the household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

20th June 2012

15. OTHER INFORMATION

Package Quantities:

Betamox Palatable Drops are packaged in bottles containing Amoxicillin Trihydrate equivalent to 750 mg amoxicillin. To enable convenient and accurate dosing a graduated pipette is provided with each pack.

Marketing authorisation No:

Vm 02000/4101

Distributed by:

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby, Northamptonshire,
NN18 9EX
United Kingdom

Approved: 22/06/2017